

### **SUMMARY OF CLAIMS**

Claims 31-33, 37, 39-45, 47, and 55-73 are pending. Claims 1-30, 34-36, 38, 46 and 48-53 are canceled. Claims 31-33, 37, 39-40, 44 and 47, are currently amended. Claims 55-73 are new. No new matter has been added.

Support for the amendments to the claims is found throughout the specification.

Support for the amendments to claim 31 can be found throughout the specification, and at least in paragraph 0197; for the term “fMRI activity” at least in paragraphs 0189-0190; for the term “localized regions of a brain” at least in paragraphs 0084, 0189-0190; for the term “subject who is still within said fMRI apparatus” at least in paragraphs 0203, 0329; and for the term “information” at least in paragraphs 0390, 0396-0397, 0399-0400.

Support for the amendment to claims 32, 39 and 47 can be found throughout the specification and at least in paragraphs 0084, and 0189-0190.

Support for the amendment to claim 37 is found throughout the specification and at least in paragraphs 0168, 0706-0716, 0727, and 0744.

Support for the amendment to claim 40 is found throughout the specification and at least in paragraphs 0006 and 0193.

Support for the amendment to claim 44 is found throughout the specification and at least in paragraphs 0140, 0150, 0366, 0390, and 0685.

Support for new claim 55 is found throughout the specification and at least in paragraphs 0396, and 0595-0599.

Support for new claim 56 is found throughout the specification and at least in paragraphs 0725-0732.

Support for new claim 57 is found throughout the specification and at least in paragraphs 0077, and 0745-0750.

Support for new claim 58 is found throughout the specification and at least in paragraph 0140.

Support for new claim 59 is found throughout the specification and at least in paragraphs 0542, and 0734-0737.

Support for new claim 60 is found throughout the specification and at least in paragraph 0396.

Support for new claim 61 is found throughout the specification and at least in paragraph 0607.

Support for new claim 62 is found throughout the specification and at least in paragraphs 0678-0689.

Support for new claim 63 is found throughout the specification and at least in paragraphs 0604-0607.

Support for new claim 64 is found throughout the specification and at least in paragraphs 0440-0455.

Support for new claim 65 is found throughout the specification and at least in paragraph 0423.

Support for new claim 66 is found throughout the specification and at least in paragraph 0628.

Support for new claim 67 is found throughout the specification and at least in paragraphs 0012, 0021, 0026, 0061, 0173 and 0266.

Support for new claim 68 is found throughout the specification and at least in paragraphs 0099-0101, 0384, 0406, 0418, 0482-0483, 0512-0513, 0588, and 0599.

Support for new claim 69 is found throughout the specification and at least in paragraph 0136.

Support for new claim 70 is found throughout the specification and at least in paragraph 279.

Support for new claim 71 is found throughout the specification and at least in paragraph 481.

Support for new claim 72 is found throughout the specification and at least in paragraph 513.

Support for new claim 73 is found throughout the specification and at least in paragraph 149.

Entry of the new claims and reconsideration is respectfully requested in light of the following remarks.

### **REMARKS**

#### **I. Interview Summary:**

Applicant wishes to thank the Examiner for courtesies extended during a telephone interview held on February 22, 2007, with Applicant deCharms and Applicant's representatives, John Storella and Peggy Radel. During the interview, Applicant and representatives discussed the proposed amended claims and the references of record with the Examiner.

#### **II. Claim Objections:**

The Examiner has objected to claim 54 because of informalities. Applicant has canceled claim 54, thereby mooting the rejection.

### **III. Claim Rejections Under 35 U.S.C. 102:**

The Examiner has rejected claims 31, 36, 37, 40, 41, 47-49 (as confirmed by telephone call), 52-54 under 35 U.S.C. 102(b) as being anticipated by Toomin et al. (U.S. Patent No. 5,995,857) (hereinafter "Toomin"). The Examiner stated "Toomin et al disclose measuring brain activity using fMRI and providing feedback to a patient." Applicant respectfully traverses the rejection.

According to the MPEP 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." In the present case, Toomin failed to disclose all of the elements of independent claim 31.

Independent claim 31 is a method for guiding a cognitive task of a subject which recites the limitations of:

"measuring activity of one or more internal localized regions of a brain of said subject, wherein said measuring is performed by an apparatus comprising an fMRI;

employing a computer executable logic that takes said measured activity and communicates information based on said measured activity to said subject who is still within said fMRI apparatus; and,

guiding a cognitive task of said subject using said information."

Toomin did not demonstrate measuring brain activity using fMRI. Rather, Toomin showed irradiating the head of a subject from without "using red and infra-red light to illuminate the brain through the translucent skull and scalp." See Col. 2, lines 62-64. "Reflected and scattered radiation, as modified by blood flow in the brain is sensed at the scalp" using a photosensor. See Col. 2, lines 58-59 and Col. 5, line 27. There are no examples in Toomin of the use of fMRI to measure brain activity. Therefore, Toomin did not anticipate any claim of the present invention.

Toomin did mention the use of MRI (not fMRI) at column 2, line 28. However, this is a gratuitous comment, as the specification is almost entirely dedicated to the infra-red methods

described above and there is no example of using fMRI or teaching on how to perform it. Further, this comment can easily be interpreted as a suggestion of using MRI (not fMRI) as a means for visualizing brain anatomy (not function) in order to register the functional information obtained using the light-based methods described by Toomin for using light to measure brain function. To the extent the mention of MRI raises an issue of obviousness, Applicant addresses this below.

Because Toomin did not anticipate independent claim 31, it could not have anticipated any claim that depends from it.

Based on the foregoing, withdrawal of the rejection of independent claim 31 and the claims that depend under 35 U.S.C. § 102 is respectfully requested.

#### **IV. Claim Rejections Under 35 U.S.C. 103:**

##### **A. Rejection over Toomin in view of Liu**

The Examiner has rejected claims 32-35, and 50 under 35 U.S.C. 103(a) as being unpatentable over Toomin et al. in view of Liu et al (U.S. Patent No. 5,844,241) (hereinafter "Liu"). The Examiner stated that Toomin disclosed measuring brain activity using fMRI and providing feedback to a patient, and that Liu demonstrated voxels. The Examiner stated that it would have been obvious to obtain measurements of small volumes as taught by Liu in the invention of Toomin. Applicant requests reconsideration.

As amended, the claims no longer refer to voxels; instead the claims refer to localized regions of a brain. Accordingly, this rejection is now moot.

In any case, Liu failed to supply the element missing from Toomin: fMRI. Liu discloses CT, not fMRI.

Again, Applicant will address the non-obviousness of using fMRI in the claimed methods below.

Applicant respectfully requests the Examiner to withdraw the rejection.

**B. Rejection over Toomin**

The Examiner has rejected claims 38, 39, 42-46 and 51 under U.S.C. 103(a) as being unpatentable over Toomin et al. The Examiner stated that the type and manner of display of information is an obvious matter of design choice to a person of ordinary skill in the art.

Applicant requests reconsideration.

Applicant points out that claim 39 is not directed to the type or manner of displaying information and, therefore, the rejection is not applicable to this claim.

Regarding pending claims 42-45, the rejection depends on the status of claim 31, from which they depend. If claim 31 is not anticipated or obvious, then claims 42-45 cannot be obvious. Applicant has argued that Toomin failed to anticipate claim 31 because it failed to demonstrate the use of fMRI. Applicant argues below that Toomin also failed to render claim 31 obvious.

**C. Rejection over Voyvodic in view of Toomin**

The Examiner has rejected claims 31-54 under 35 U.S.C. 103(a) as being unpatentable over Voyvodic "Real-Time fMRI Paradigm Control" (hereinafter "Voyvodic") in view of Toomin. The Examiner stated that Voyvodic discloses all the claimed subject matter, including fMRI, except employing computer logic to communicate information to the subject in real time. The Examiner stated that it would have been obvious to use the computer as shown by Toomin to communicate directly to a patient via a visual display as shown by Voyvodic. Applicant respectfully traverses the rejection.

A *prima facie* case of obviousness cannot be established against the claims as presently amended, as the references did not teach or suggest a combination or modification of previous inventions to arrive at all the claim limitations of the present invention with any reasonable expectation of success.

Voyvodic taught a method of taking fMRI activity measurements of a brain when subjects were given specific tasks to perform. See Voyvodic, page 94, col. 2, para 4. However, as the Examiner recognized, Voyvodic did not teach or suggest the essential feature of the present invention, communicating information based on the measured activity of one or more

localized regions of the brain to the subject who is still within an fMRI apparatus; as recited in claim 31. Simply put, Voyvodic did not ‘close the feedback loop’ as he did not take the information about the activity being measured and communicate it back to the subject.

In Voyvodic, information about the activity measurements was communicated to the operator only. On page 94 of Voyvodic, a subject performed activities while in the fMRI scanner. The operator saw the brain activity changing as the subject performed the activities. “The results were displayed on an X-windows terminal in the scanner control room.” See Voyvodic, page 94, col. 1, para 4 to col. 2, para 3. The only information that the subject received were “paradigms” which had no content relating to the fMRI activity measurements being made. See Voyvodic, page 94, col. 2, para 4. The “paradigms” of Voyvodic were selected from:

“watching a central fixation crosshair on a black background, around which appeared radially moving white dots in animated 20-s blocks; they were instructed to move a joystick and randomly press two button box keys during the animated sequences . . . [, i]n the second paradigm, subjects fixated on a central crosshair while a hemifield, 8 Hz flickering checkerboard rotated about the fixation point . . . making a complete revolution every 32 s . . . [, and f]or the third paradigm, subjects alternated between 30-s blocks in which they either read simple sentences . . . and answered associated true/false questions using a button box, or scanned a line of consonant-only text and then randomly pressed a button” . . . See Voyvodic, page 94, col.1, para 4.

The information the subjects received (“the paradigms”) did not change depending on the activity that was measured during the performance of that activity, rather the choice of paradigms was arbitrary and fixed. There is no indication that the subject ever received information about brain activity in a localized region or that the subject used that kind of information to guide a cognitive process.

Furthermore, if the invention had been obvious in view of Voyvodic, Voyvodic had ample opportunity to mention it: Voyvodic presents an extensive discussion of the many potential real or potential uses of their system. In the discussion presented on pages 101-105, at least nine separate existing or potential uses of the software and system are presented for “real time fMRI Paradigm Control”. None of these describe the essential feature of the present

invention: communicating information based on the measured activity of one or more localized regions of the brain to the subject in order to guide their behavior. The possibility is not even remotely suggested.

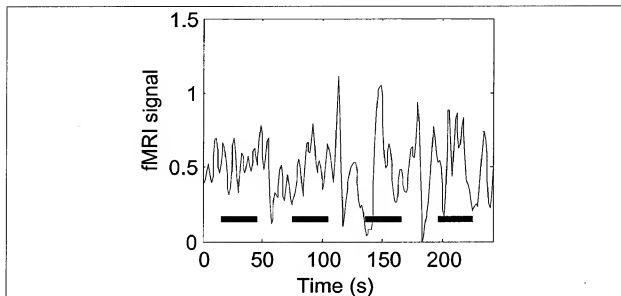
The combination of Voyvodic with Toomin's teaching of communicating information to a subject failed to provide a person of ordinary skill in the art with a reasonable expectation that one could successfully use fMRI in the manner set forth in claim 31. There are several reasons why this is so.

First, at the time, it was not clear that the information provided by fMRI was of high enough quality to contain useful information to serve as the basis for guiding the tasks of a subject. At the time of Toomin's invention, most fMRI studies involved having subjects perform a task like tapping their finger or looking at an image repeatedly (e.g., 10 times), collecting data from a large number of subjects (e.g., 12), and then averaging the results to produce a map of which brain areas are activated using specialized software. These are the type of studies that Toomin referred to when it stated "[w]ith the advent of SPECT, PET and fMRI, blood flow in various brain areas is increasingly being correlated with various brain disorders". See Toomin, col. 1, lines 17-19. When successful, this can produce correlation maps of which areas of the brain are involved in conducting a task, or involved with a disease.

However, the fact that it is possible to make correlation maps on average data, particularly from groups, does not make it obvious that one could use fMRI information from a single moment in time or from a single trial taken from a single individual to try to successfully guide the cognitive processes of that individual.

The figure below, generated by Applicant from the brain of a single subject on a single trial, shows how noisy an rtMRI signal can be:





This figure shows the timecourse of fMRI activation measured each second over four minutes from a region of interest in the somatomotor cortex in a single subject, prior to rtfMRI-based training. During periods shown with the heavy black bars, the subject was instructed to try to increase the activation measured from the target region of interest. As one can see, this signal is noisy: The signal from times of increased activation are difficult to distinguish from the signal from lower activation. It was not clear before the invention was made that a subject could use such a signal successfully to learn to control their cognitive processes, such as to learn to control activation in this brain region of interest using cognitive strategies. The fact that it can be done is a surprising result that supports Applicants contention that the invention was not obvious.

Second, it was not obvious whether the hemodynamic delay inherent in the brain's blood flow signals would make guiding the cognitive process of a subject using rtfMRI impossible. There is an inherent delay of about 3-5s from the time of neural activation to the time that the fMRI signal shows a meaningful increase. Given that training signals are ideally closely time-locked, it was therefore not obvious whether an fMRI signal could be meaningfully used to train subjects or guide their cognitive processes. It could have simply been confusing to them.

Third, it also was not clear at the time that information about brain activity produced by fMRI could be successfully used to guide the cognitive tasks of a subject who received that

information. This type of information is qualitatively different than the signals collected by Toomin and, therefore, there is no basis for comparison or extrapolation.

Thus, regardless of what Toomin showed about the utility of information from light reflected from inside the brain, one could not reasonably have extrapolated that utility to fMRI activity information: There was no basis to compare the information.

In sum, Voyvodic did not anticipate the invention at least because it did not show the communication of brain activity measurements to a subject using a computer executable logic. Toomin in combination with Voyvodic failed to render the invention obvious because at the time, a person of ordinary skill in the art would not have had a reasonable expectation that the information from an fMRI provided a person in the apparatus information of sufficiently high quality to be meaningful or that such information, even if meaningful, could be acted upon by the subject.

Based on the foregoing, a *prima facie* case of obviousness can not be established against claim 31 over Voyvodic in view of Toomin. Thus, Applicant respectfully requests withdrawal of the rejection of claim 31 and claims dependent from it, under U.S.C. 103(a).

**CONCLUSION**

In light of the remarks and amendments set forth above, Applicant believes that the claims are in condition for allowance. Applicant respectfully solicits the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any fees that may be required in connection with this submission, including petition fees and extension of time fees, and to credit any overpayments to Deposit Account No. 23-2415 (Attorney Docket No. 27969-702.201).

Respectfully submitted,

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